Medical Device Registration in Russia: Complete Process, Requirements, Cost & Timeline (2026 Guide)

Introduction
Medical Device Registration in Russia is a mandatory process for manufacturers to legally sell devices. It ensures safety, quality, and compliance with regulatory standards set by Roszdravnadzor.

What is Medical Device Registration?
It is a legal approval system that evaluates product safety, performance, and effectiveness before allowing market entry.

Regulatory Authority
Roszdravnadzor is responsible for approvals, documentation review, and compliance monitoring.

Classification
Class 1 – Low Risk
Class 2a – Medium Risk
Class 2b – Medium-High Risk
Class 3 – High Risk

Registration Process
1. Appoint local representative
2. Prepare documentation
3. Conduct testing
4. Clinical trials
5. Submit application

6. Receive certificate

Documents Required
Application form, ISO 13485, Free Sale Certificate, Technical file, Clinical data, Labeling details

Timeline
Class 1: 4–6 months
Class 2a/2b: 6–10 months
Class 3: 10–14 months

Cost
Low-risk: $5,000 – $15,000
High-risk: $20,000+

EAEU Advantage
Single registration gives access to Russia, Kazakhstan, Belarus, Armenia, Kyrgyzstan

Challenges
Language barrier, complex regulations, testing requirements, updates in rules

Expert Tips
Work with consultants, ensure proper documentation, follow ISO standards

Conclusion
With proper planning and compliance, companies can successfully enter the Russian market.

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